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REMARKS

Regarding the Amendments

Claims 1, 5, 11 and 12 have been amended as set forth in the above Complete Listing of the Claims. In particular, claims 1 and 11 have been amended as suggested by the Examiner, to include a PBMC-specific promoter operably linked to the transgene. Support for such amendment may be found in the specification on page 21-22. Claims 1 and 11 have also been amended to recite that the transgenic rat is a model for human HIV infection, as suggested by the Examiner. Support for this amendment may be found throughout the specification, in particular at page 5, lines 19-23 and pages 17-22, under the heading "Lentiviral Transgenes and Transgenic Animals Produced Therewith." Claim 5 has been amended as suggested by the Examiner, to clarify that the CD4 protein and the CCR5 protein are encoded by different transgenes. Such amendment is supported by original claims 1 and 2, reciting two transgenes, from which claim 5 depends. Withdrawn claim 12 has been amended to correct a prior typographical error, identifying the PBMC cells as "PMBC."

Accordingly, as amended, the claims are supported by the specification and the original claims and do not add new matter, as defined by 35 U.S.C. § 132. Nor do the amendments require a new search, or raise new issues for consideration because they merely address issues already raised by the Examiner or define Applicants' invention more clearly. In fact, with the exception of correction of the typographical error of "PMBC," all amendments to the claims have been made in response to suggestions by the Examiner.

It is submitted that the amendments place the claims in condition for allowance or in better condition for appeal by reducing the number of issues for consideration on appeal. The amendments were not made earlier in the prosecution because it is maintained that the previously pending claims were allowable. Since the amendments do not add new matter or require a new search or consideration, and place the claims in condition for allowance or in better condition for appeal, entry of the amendment is respectfully requested.

Thus, upon entry of the amendments, claims 1-21 will be pending, of which 12-21 are withdrawn.

Priority Determination

It is stated in the Office Action mailed December 13, 2006 that the present application is not given the April 9, 1998 effective filing date of the prior filed application U.S. Application No. 09/058,113 (now issued U.S. Patent No. 6,156,952), as that application does not provide support

or enablement for the claimed invention. Applicants respectfully disagree.

In the Amendment and Response mailed October 2, 2006, Applicants stated that the prior application provides support for the combination of a human CD4/CCR5 transgenic rat or human CD4/CXCR4 transgenic rat. Those arguments and specific citations are incorporated by reference herein without having to restate the same.

In the present Office Action, the Examiner has stated that the arguments of the Amendment and Response mailed October 2, 2006 are not persuasive, because the amended claims submitted therein were not enabled by the specification. Applicants direct the Examiner's attention to the enablement discussion below, clearly demonstrating the enablement of the claims presented herein for entry. Specifically, claims 1 and 11 have been amended as set forth above, in accordance with the Examiner's suggestion, to include a promoter with the transgene encoding at least a portion of a CD4 protein. As discussed below, such a transgenic rat is fully supported and enabled by the instant specification. Furthermore, inclusion of such a promoter is also discussed in the specification of the priority document, U.S. Patent No. 6,156,952 at column 13, lines 31-53.

As the present claims are enabled in both the present specification and the specification of U.S. Patent No. 6,156,952, it is respectfully submitted that the priority date of April 9, 1998, as originally claimed, is the correct priority date. Application of the April 9, 1998 date to the present claims is warranted and respectfully requested.

Rejection of Claims 1-11 Under 35 U.S.C. §112, Enablement

Claims 1-11 were rejected under 35 U.S.C. §112, first paragraph as lacking enablement.

However, the Examiner stated that:

“...the specification...[is] enabling for a transgenic rat, whose genome comprises a transgene encoding a portion of or a full length CD4 protein that binds to gp120 and CCR5 or CXCR4, if present, and mediates entry of HIV and wherein the CD4 transgene contains a PMBC [sic] specific promoter resulting in expression of the CD4 on PMBCs [sic] of the transgenic rat and wherein the transgenic rat further comprises a second transgene in its genome encoding a CCR5 or CXCR4 wherein the second transgene comprises a PMBC [sic] specific promoter resulting in expression of CCR5 or CXCR4 on PMBCs [sic]...”

As amended, claims 1 and 11 each include a PBMC-specific promoter which is operably linked to the CD4 transgene to promote expression of the CD4 on the surface of the rat's PBMCs. As

indicated by the Examiner, the claims are enabled, as amended. Withdrawal of the rejection is therefore respectfully requested.

Rejection of Claim 5 Under 35 U.S.C. §112, New Matter

Claim 5 has been rejected under 35 U.S.C. §112, first paragraph as containing new matter. Specifically, the Examiner has rejected the claim for use of the term "the transgene" in the portion of the claim that states: "wherein the at least a portion of a CD4 protein and the at least a portion of CCR5 encoded by the transgene..." As amended, the term "the transgene" in claim 5 has been amended to "the respective transgenes," indicating the two different transgenes, one encoding CD4 and one encoding CCR5, as set forth in claims 1 and 2, respectively, under which claim 5 is dependent.

Accordingly, withdrawal of the rejection of claim 5 under 35 U.S.C. §112, first paragraph is respectfully requested.

Rejection of Claim 5 Under 35 U.S.C. §112, Indefiniteness

Claim 5 is rejected under 35 U.S.C. §112, second paragraph as being indefinite. Specifically, the Examiner has rejected the claim for use of the phrase "wherein the at least a portion of a CD4 protein and the at least a portion of CCR5 encoded by the transgene..."

As amended, claim 5 is clear in the recitation of "the respective transgenes" to indicate the presence of multiple transgenes (i.e., CD4 and CCR5). Accordingly, withdrawal of the rejection of claim 5 under 35 U.S.C. §112, second paragraph is respectfully requested.

Rejection of Claims 1-11 Under 35 U.S.C. §102(e)

The rejection of claims 1-11 under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent No. 6,372,956 B1 (hereinafter "Goldsmith") has been maintained in the Office Action mailed December 13, 2006. Applicants respectfully traverse such rejection, and reiterate the fact that Goldsmith is not prior art to the present application.

As stated above, the claims of the present application are entitled to the priority date of April 9, 1998, the effective filing date of the prior filed application U.S. Patent No. 6,156,952. As Goldsmith was filed on December 23, 1999, it is not available as prior art to the present application. Withdrawal of the rejection is therefore respectfully requested.

Rejection of Claims 1-11 Under 35 U.S.C. §103

Claims 1-10 are rejected under 35 U.S.C. §102(e) as allegedly obvious over Browning et

al. Applicants respectfully traverse such rejection.

In order for an invention to be obvious, the difference between the subject matter of the application and the prior art must be such that the subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. In order to meet this standard, the cited references must teach or suggest all of the elements of the claimed invention. It is respectfully submitted that Browning et al. does not teach or suggest all of the elements of the claimed invention. Specifically, Browning et al. does not teach a transgenic rat.

Applicants have previously pointed out, in the Amendment and Response filed October 2, 2006, that while mice and rats are both rodents, they are distinctly different species and are not directly analogous to one another, as is known to those of skill in the art.

Furthermore, because of the differences between rats and mice, one of skill in the art would not have a reasonable expectation of success in producing a transgenic rat for use as a human model of infection from the transgenic mouse teachings of Browning et al. Indeed, the Browning et al. reference states that HIV infection was not seen in the transgenic mice.

The Examiner has stated that the foregoing line of argumentation is not persuasive, as the claims of the invention do not require that the transgenic rat model human infection. Accordingly, upon the Examiner's suggestion, claims 1 and 11 have been amended to include the proviso "wherein the transgenic rat is adapted to model human HIV infection."

As the claimed invention provides a transgenic rat adapted to model HIV and AIDS progression in humans, the present invention fulfills a prior need in the art for an animal model from which to study human infection. A transgenic rat of the claims provides such a model. As one of skill in the art would have known that a mouse model would not have modeled human infection and would have known that mice and rats are not directly analogous, one of skill in the art would not have had a reasonable expectation of success in creating a transgenic rat from the teachings of Browning et al. to model human infection, as has been done by applicants in making the present invention.

As Browning et al. does not describe a transgenic rat and one of skill in the art would not have been motivated to combine the teachings of Browning et al. into a rat to model human infection, due to lack of any reasonable expectation of success, Browning et al. does not render the claimed invention obvious. Accordingly, withdrawal of the rejection of claims 1-10 under 35 U.S.C. § 103 (a) as being obvious over Browning et al. is respectfully requested.

Additionally, claim 11 has been rejected under 35 U.S.C. §103(a) as obvious over Sawada et al. As set forth above, the claims of the present application are entitled to the priority date of April 9, 1998, the effective filing date of U.S. Patent No. 6,156,952. As Sawada et al. was published in May 1998, it is not available as prior art to the present invention. Withdrawal of the rejection is therefore respectfully requested.

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CONCLUSION

Based on the foregoing, all of Applicants' pending claims 1 to 11 are patentably distinguished over the art, and are in form and condition for allowance. The Examiner is requested to favorably consider the foregoing and to responsively issue a Notice of Allowance.

No fees are believed to be due for the filing of this paper. However, should any fees be required or an overpayment of fees made, please debit or credit our Deposit Account No. 08-3284, as necessary.

If any issues require further resolution, the Examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same.

Respectfully submitted,

Date: February 13, 2007

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